

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS  
REPORTED IN D. D. N. J. NOS. 5061-5080

*Adulteration*, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; Section 501 (d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor.

*Misbranding*, Section 502 (a), the labeling of the article was false and misleading; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

*New-drug violation*, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

5061. Honey with Royal Jelly. (F. D. C. No. 39022. S. No. 33-991 M.)

QUANTITY: 17 1-lb., 8-oz. jars, at Tulsa, Okla., in possession of Akin Natural Food.

SHIPPED: 2-29-56, from Los Angeles, Calif., by Western Commerce Corp.

LABEL IN PART: (Jar) "Topaz Brand Cream Of The Tropics Honey With Royal Jelly Wonder Food Of The Queen Bee Each teaspoonful contains approx. 100 mg. of Royal Jelly."

ACCOMPANYING LABELING: (Leaflet) "Royal Jelly by R. B. Willson."

RESULTS OF INVESTIGATION: The above-mentioned leaflet was printed locally for the consignee.

LIBELED: 4-6-56; amended 5-22-56, N. Dist. Okla.

CHARGE: 502 (a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for nervous and glandular disorders, including aging, cerebral neuritis, arthritis, autointoxication from tobacco, asthma, failing eyesight, sterility in women, impotence in men, and deficient lactation in women; and 505 (a)—the article was a new drug which may not be lawfully introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 6-12-56. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE  
DIRECTIONS OR WARNING STATEMENTS

5062. Elemin vitamin and mineral tablets. (F. D. C. No. 37266. S. No. 5-566 M.)

INFORMATION FILED: 8-3-55, E. Dist. Wis., against John P. Sheeran, Milwaukee, Wis.

ALLEGED VIOLATION: 11-16-54, the defendant, in the course of a sales talk to an individual, made oral representations holding out the article as an effective treatment for the diseases, symptoms, and conditions set forth below, which acts resulted in the article being misbranded while held for sale.

**LABEL IN PART:** (Carton) "Elemin Supreme Formula G & J Multiple Vitamins This Package Contains a 60 Day Supply SUPREME FORMULA is packaged in sanitary, hermetically sealed Pocket Paks, each containing 2 Elemin Mineral Tablets and 1 G & J Multiple Vitamin Tablet."

**CHARGE:** 502 (f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the article was intended, namely, colds, sinus infections, heart trouble, diabetes, asthma, high blood pressure, ulcerated stomach, and arthritis.

**PLEA:** Not guilty.

**DISPOSITION:** The case came on trial before the court without a jury on 2-17-56, and was concluded on the same day. The court took the case under advisement; on 3-28-56, the court handed down a finding of guilty against the defendant. On 6-18-56, the court suspended imposition of sentence and placed the defendant on probation for 1 year.

**5063. Vitamin and mineral food supplement.** (F. D. C. No. 38452. S. Nos. 7854/5 M.)

**QUANTITY:** 46 cases, each containing 12 packages and each package containing 1 186-tablet bottle of *mineral tablets* and 1 62-capsule bottle of *vitamin capsules*, at Oklahoma City, Okla., in possession of K. V. Products Co.

**SHIPPED:** 7-29-55, from Glendale, Calif.

**LIBELED:** 9-20-55, W. Dist. Okla.

**CHARGE:** 502 (f) (1)—the labeling of the article, while held for sale, failed to bear adequate directions for use for the purposes for which the article was intended, namely, in the treatment of rheumatism, asthma, heart conditions, loss of hair, nosebleed, and for cleaning the blood, which were the conditions and purposes for which the article was offered orally by Mrs. Bertha Lee Wilson, a representative of K. V. Products Co.

**DISPOSITION:** 6-7-56. Default—destruction.

**5064. Cal-O-Dine.** (F. D. C. No. 38461. S. No. 24-750 M.)

**QUANTITY:** 26 2-qt. jugs at Seattle, Wash., in possession of Emil Gellerman.

**SHIPPED:** 8-15-55, from Alameda, Calif.

**LABEL IN PART:** "Cal-O-Dine \* \* \* A Dietary Source of Iodine Consists of Potassium Iodide In Processed Sea Water."

**LIBELED:** 9-29-55, W. Dist. Wash.

**CHARGE:** 502 (f) (1)—the labeling of the article, while held for sale, failed to bear adequate directions for use for the purposes for which it was intended, namely, in the treatment of heart disease, arthritis, stomach troubles, ulcers, paralysis, cataracts, tumors, dizzy spells, pernicious anemia, goiters, burns, and bruises, which were the conditions for which the article was offered by Emil Gellerman.

**DISPOSITION:** 8-28-56. Default—destruction.

#### **DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS**

**5065. Various drugs.** (Inj. No. 280.)

**COMPLAINT FOR INJUNCTION FILED:** 4-29-54, E. Dist. N. Y., against Bonded Laboratories, Inc., Brooklyn, N. Y., and Hans Lowey, president of the corporation.